DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 20, 2015

Miami Device Solutions, LLC
% Mr. Peter J. Mincieli
HealthLink Associates, Incorporated
631 South East 11th Street
Pompano Beach, Florida 33060

Re: K141493
Trade/Device Name: Proximal Humerus Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 23, 2014
Received: December 29, 2014

Dear Mr. Mincieli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K141493

Device Name: **Proximal Humerus Plating System**

The MDS Proximal Humerus Plating System is intended to provide internal fixation of fractures of the proximal humerus.

Prescription Use X and/or Over the Counter Use ___

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Name of Applicant:	Miami Device Solutions, LLC Markku Biedermann 7620 NW 25th Street, Unit 3 Miami, FL 33122 Phone: (786) 422-1400 Fax: (786) 422-1401
510(k) Contact:	Healthlink Associates, Inc. Peter J Mincieli 631 SE 11th Street Pompano Beach, FL 33060 Phone: (954) 818-9204 Fax: (800) 215-9489
Date:	02-19-2015
Trade Name:	Proximal Humerus Plating System
Common Name:	Single/Multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification:	Class II per 21 CFR 888.3030
Device Product Code:	HRS / HWC
Predicate Devices:	Arthrex Humeral Fracture Plates and Screws – K041965 Smith and Nephew Inc. Peri-Loc Locking Bone Plates and Locking Bone Screws for the Upper -Extremity - K051735 Zimmer Universal Locking System, 3.5mm - K081759
Device Description:	The Proximal Humerus Plating System is an internal fixation plate system to be used for proximal humerus fractures. The system consists of plates, screws, and locking caps. The Proximal Humerus Plates are available in two lengths, and are side-specific. The Proximal Humerus Plating System Screws are 3.5mm in diameter and available in various lengths.
Intended Use:	The Proximal Humerus Plating System is indicated for internal fixation of fractures of the proximal humerus.
Comparison to Predicate Device:	The Proximal Humerus Plating System has the same intended use, similar performance characteristics, and is similar in design and materials to the predicate devices listed above, with the exception of the Smith and Nephew Self-Tapping Locking Screw which is made of Stainless Steel.

Performance Data (Non-clinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (laboratory/performance) testing demonstrate that the device is safe and effective.

Substantial equivalence was demonstrated in the performance testing section of the submission by comparing the design and testing according to ASTMF382-99, Standard Test Method for Metallic Medical Bone Plates and ASTM F543-07, Standard Specification and Test Method for Metallic Bone Screws which shows that the Proximal Humerus Plating System performs as well as the predicate devices. Comparison of the design, intended use, and testing demonstrate that the Proximal Humerus Plating System performs as well as the predicate devices and should thereby be considered substantially equivalent.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.